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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,184	10/21/2003	Timothy J. Foster	P06335US05/BAS	8504

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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,184

Applicant(s)

FOSTER ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-20-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Group II in the reply filed on 12-8-2004 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-22 are pending. Claims 1-9 and 18-22 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 10-17 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 1-20-2004 is acknowledged. An initialed copy is attached hereto.

Specification

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Additionally, the current status of each prior nonprovisional application must be provided.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10, 13-14 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 18 and 22 of copending Application No. 10/378,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to methods of treating or preventing coagulase-negative staphylococcal infections utilizing antibodies to the *Staphylococcus epidermidis* protein SdrG. Both claims sets utilize the same reagents and same method steps to achieve the same goal. Consequently, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to antibodies to the *Staphylococcus epidermidis* SdrG protein which can treat or prevent coagulase-negative staphylococcal infections upon their administration to a subject.

The claims are drawn to a vast genus of antibodies, the members of which recognize the *Staphylococcus epidermidis* SdrG protein wherein said antibodies can treat or prevent coagulase-negative staphylococcal infections. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of antibodies that bind to the *Staphylococcus epidermidis* SdrG protein one must describe not just those determinants that would elicit an immune response to the SdrG polypeptide but which determinants would give rise to antibodies that would have therapeutic and/or prophylactic efficacy against coagulase-negative staphylococcal infections since a given determinant can induce antibodies that bind to the SdrG

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polypeptide but lack any therapeutic and/or prophylactic efficacy.

The specification does not describe with any degree of specificity a single member of the genus of epitopes of SdrG to which the members of the claimed genus of antibodies must bind, wherein said antibodies can effectively treat or prevent coagulase-negative staphylococcal infections such that the specification might reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Moreover, the specification does not disclose distinguishing and identifying features of a representative number of members of the genus of antibodies to which the claims are drawn, such as a correlation between the structure of the immunoepitope its recited function (to induce/bind antibodies with therapeutic and/or prophylactic efficacy against coagulase-negative staphylococcal infections), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of antibodies. Additionally, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes on which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of antibodies that bind to the *Staphylococcus epidermidis* SdrG protein and have therapeutic and/or prophylactic efficacy against coagulase-negative staphylococcal infections.

MPEP § 2163.02 states, “[a]n objective standard for determining compliance with the

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written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual

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reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was “ready for patenting” by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus” (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. (*Nature Biotechnology* 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an “epitope” (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus antibodies that bind to the *Staphylococcus epidermidis* SdrG protein and have therapeutic and/or prophylactic efficacy

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against coagulase-negative staphylococcal infections. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of antibodies to which the claims refer.

Claims 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Breadth of the claims

The rejected claims are drawn to the prophylactic or therapeutic use of antibodies that bind to the *Staphylococcus epidermidis* SdrG polypeptide.

Working Examples/Guidance of Specification

The specification provides no working examples demonstrating the efficacy of claimed methods. The working examples are limited to methods of identifying Sdr genes, expression of said genes and the sequencing of the resulting Sdr gene products. The specification is silent with respect to the use of specific anti-SdrG antibodies for the treatment or prevention of coagulase-negative staphylococcal infections.

State of the prior art and Unpredictability of the art

To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The specification, as filed, does not set forth that the claimed use of the claimed antibodies provide

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any sort of protective immunity in any model system that can be extrapolated to humans or any other mammal. Applicant states that the claimed antibodies "... are useful as blocking agents to prevent or inhibit the binding of coagulase-negative staphylococci." in a prophetic sense but fails to demonstrate any therapeutic or prophylactic efficacy in any animal system (. The specification is silent as to which polynucleotide/host/microorganism would be effective to prevent a given condition associated with infection by a given staphylococci species. The examples, disclosed in the instant specification, are limited to the identification Sdr genes, expression of said genes and the sequencing of the resulting Sdr gene products. While the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition in any given animal is quite unpredictable. Given the lack of success in the art, the lack of working examples and the unpredictability of the generation of protective immunity, the specification, as filed, does not provide enablement for methods of preventing coagulase-negative staphylococcal infections, comprising administering to a patient antibodies to the *Staphylococci epidermidis* SdrG protein.

Additionally, the specification provides no guidance as to what antibodies would be "therapeutic" for a given coagulase-negative staphylococcal infection. To be a treatment composition, said composition must provide a benefit to the subject to which it is administered. The specification, as filed, does not set forth which "antibody", if any, would provide a benefit when administered within the context of a coagulase-negative staphylococcal infection. While the skill in the arts of medicine, pharmacology and immunology is high, to date, prediction of therapeutic efficacy for any given composition is quite unpredictable. Consequently, one of skill in the art would not be able to contemplate which "antibody" would be an effective "treatment" for a given coagulase-negative staphylococcal infection. Given the lack of success in the art, the

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lack of working examples and the unpredictability of therapeutic efficacy, the specification, as filed, does not provide enablement for methods of treating coagulase-negative staphylococcal infection, comprising administering an antibody that binds to the *Staphylococci epidermidis* SdrG protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is rendered vague and indefinite by the use of the phrase “amino acids 32 to 961 of SEQ ID NO:10”. It is unclear what Applicant is referring to since SEQ ID NO:10 consists of only 930 amino acid residues.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Douchette-Stamm et al. (U.S. Patent 6,380,370 – IDS).

Douchette-Stamm et al. disclose a polypeptide from *Staphylococcus epidermidis* (see SEQ ID NO:5314) with 99.9% sequence homology to the SdrG protein of the instant application (SEQ ID NO:10). Douchette-Stamm et al. further disclose antibodies that specifically bind to said polypeptide (see column 9, lines 8-22). Finally, Douchette-Stamm et al. disclose the use of said antibodies in methods “...for preventing or treating disease caused by certain bacteria”, including *S. epidermidis*...” (i.e. bacterial infection)[see column 10, lines 42-50]. Since the polypeptide used for antibody production by both Douchette-Stamm et al. and the instant invention are the same, the resulting antibodies would necessarily have the same specificities and immunological efficacies. Consequently, Douchette-Stamm et al. anticipate all the limitations of the instant claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Zeman

April 13, 2005